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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,674	08/08/2006	Muthunadar P. Periasamy	1667 WO/US	4628

76656 7590 02/03/2011

Patent Docket Department  
Armstrong Teasdale LLP  
7700 Forsyth Boulevard  
Suite 1800  
St. Louis, MO 63105

EXAMINER
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SAMALA, JAGADISHWAR RAO

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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02/03/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,674	<b>Applicant(s)</b> PERIASAMY ET AL.	
	<b>Examiner</b> JAGADISHWAR R. SAMALA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 10-11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 10-11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Remarks filed on 11/05/2010.

- Claims 1, 2, 4, 6, 8, and 10-14 have been amended.
- Claims 5, 7 and 9 have been canceled.
- Claims 1-4, 6, 10-11 and 13-20 are pending and presented for examination.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 10-11 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felder et al (US 5,695,742) in view of Sovak (US 5,698,739) **are maintained** for reasons of record in the previous office action filed on 07/07/2010.

Applicants arguments filed on 11/05/2010 have been fully considered but they are not persuasive.

Applicant argues that one of ordinary skill in the art would lack motivation to combine the monomers of Felder with the dimmers of Sovak in order to arrive at the composition required in Applicant's claim 1, which unexpectedly has a favorably lower osmolality.

This argument is not persuasive since the motivation to combine the references does not necessarily have to match with what applicant wants to accomplish. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). In the instant case, Felder et al (US 5,695,742) teaches injectable formulations of iodinated contrast media for X-ray imaging. It was unexpectedly found that injectable aqueous compositions, comprising mixtures of non-ionic iodinated aromatic compounds

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monomer and dimmers, not only have an intermediate osmolality compared to the pure solutions of monomer and dimmer, and are also isoosmolal or isotonic to the plasma but they also have a lower viscosity than the expected, and a lower toxicity than those shown by the corresponding pure solutions of monomer and dimmer, while Sovak (US 5,698,739) teaches that non-ionic contrast compounds have low osmolality, while at the same time maintaining moderate to low viscosity.

Applicant argues that Felder reference, the "A" groups disclosed therein are all large and sterically shield the adjacent iodine moieties. Furthermore, these large "A" groups contain at least 2 hydroxyl groups, which increase hydrophilicity and thereby aid with water solubility. This argument is not persuasive sine the "A" groups disclosed therein are primary carboxamide groups and does not shield the iodine moieties, and compounds have an intermediate osmolality and low viscosity. Felder teaches that the "A" optionally substituted by hydroxyl groups and is not necessary to contain in the compound.

Applicant argues that the monomer of Formula I in Applicants' claim 1 do not include primary carboxamide moieties and thus do not contain exposed iodine moieties or the hydrophobic regions thereto. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413,208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091,231 USPQ 375 (Fed. Cir. 1986).

In this case, the Sovak patent is relied upon to show that it is known in the art to non-ionic contrast media and formulations for X-ray imaging procedures, wherein the contrast media have the dimeric compound, i.e. malonic acid bis-[{3-N-(2,3-dihydroxypropyl)- carbamoyl)-5-carbamoyl}-2,4,6-triiodo-N-(2,3-dihydroxypropyl)anilide, (col. 3 lines 26 - 29), which has the same chemical structure as iosimenol, while the Felder patent shows an equivalence that is recognized in the art for a injectable aqueous compositions, comprising mixtures or non-ionic iodinated aromatic compounds monomers of type (I) and dimmers of type (II) contrast agents useful for X-ray imaging of human body.

### Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./  
Examiner, Art Unit 1618

/Jake M. Vu/  
Primary Examiner, Art Unit 1618